CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 19-452/S017

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATIO DDDDP (HFD-540)	N 2. NDA NUMBER 19-452
3. NAME & ADDRESS OF	F APPLICANT	4. AF NUMBER
Hill Dermaceuticals. Inc. Attention: Rosario G. Ramirez Director, Medical at 2650 South Mellonville Avent Sanford, Florida 32773	nd Regulatory Affairs	
		5. SUPPLEMENT(s) NUMBER(s)DATE(s (SE5) N 19-452/S017 dated 10/9/00
6. NAME OF DRUG Derma-Smooth/FS	7. NONPROPRIET fluocinolone aceto	
8. SUPPLEMENT(s) PRO	VIDES FOR: 9.	AMENDMENTS AND OTHER (REPORTS, etc.) DATES S/A dated 7/27/01 & 8/31/01
SE5- Provides for revised laboulder.	eling to include the pediatr	ric population of 2 years and
10. PHARMACOLOGICAL Anti-inflammatory Agent 12.RELATED CATEGORY IND/NDA/DMF(s)		11.HOW DISPENSED xxx Rx OTC
13. DOSAGE FORM(s)	14. POTENCY(ies	s)
Topical Oil	0.05%	

15. CHEMICAL NAME AND STRUCTURE

	16. RECORDS AND REPORTS		
m.w	CURRENT		
CAS Registry No	X Yes No		
	REVIEWED		
	X Yes No		

17. COMMENTS

The applicant submitted an efficacy supplement on 10/9/00 to provide for the pediatric use for this drug product. Revised labeling (PI) was submitted to reflect this change. In addition, the technical portion of the labeling was revised per 7/27/01 amendment as follows:

- (1) The ingredient, peanut oil NF, was preceded by the word "refined".
- (2) The temperature range for storage condition was changed to 68° to 77°F (20°-25°C) to comply with the official compendium, USP 24/ NF 19.

This labeling was reviewed and found acceptable from a technical standpoint with two exceptions:

- (1) In keeping with the spirit of the USP, the temperature range is not correctly stated. Instead of listing the temperature range in Celsius first, followed by Fahrenheit range second, the firm listed the temperature range in Fahrenheit first, followed by the Celsius range second. In this regard, the controlled room temperature should be described as 20°-25° C (68° to 77°F). Therefore, the firm should be advised to list the temperature range for the controlled room temperature as indicated in the USP. This minor revision may be done at the next printing of the package insert.
- (2) The supplement did not include container labels. It is assumed that this labeling is unchanged from a technical standpoint.

The applicant amended the supplement on 7/21/01 and 8/31/01 to include the required CMC and environmental statements as requested. This chemistry review covers this information:

Chemistry, Manufacturing and Controls:

Acceptable

The firm certifies that the proposed changes in the supplemental application do not affect the Chemistry, Manufacturing and Controls section as submitted in the NDA (see 7/27/01 Amendment).

Environmental Impact:

Acceptable

The firm requested a categorical exclusion per 21 CFR 25.31(a) since the estimated concentration of active moiety into the aquatic environment is well below 1 part per billion (ppb). In support of this claim, the calculation of the EIC was submitted in amendment dated 8 /31/01. information:

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement. The PM should convey the following information as requested under items (1) and (2) above.

cc: Orig: NDA 19-452

HFD-540

HFD-540/KO

HFD-540/Hill

HFD-540/Wright

HFD-540/EGPappas

HFD-540/WHDeCamp:R/D initialed _

19. RF	EVIEWER			
NAME	SIGNATURE		ΓURE	DATE COMPLETED
Ernest G. Pappas				09/25/0
DISTRIBITION	ORIGINAL	IACKET	REVIEWER	DIVISION FILE